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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,380	07/12/2001	Jane H. Morse	62430-A/JPW/SHS	1634

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EXAMINER

HORLICK, KENNETH R

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	09/904,380	MORSE ET AL.
	Examiner Kenneth R Horlick	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 October 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,7,8,10-19,21-49,51-53,55-57,59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) 53,55,57,59 and 60 is/are withdrawn from consideration.
- 5) Claim(s) 56 is/are allowed.
- 6) Claim(s) 1-5,7,8,49,51 and 52 is/are rejected.
- 7) Claim(s) 10-19 and 21-48 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 July 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

1. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged.

The traversal is on the ground(s) that the inventions are not independent, and no serious burden would be put on the examiner in examining all the groups together. This is not found persuasive because it is well established in U.S patent practice that distinctness alone, rather than both independence and distinctness, is sufficient as a criterion for proper restriction. Further, the response provides no substantive argument as to why the restriction requirement is in error as not establishing serious burden of search; the requirement sets forth that the different groups of inventions both have different classification and involve non-overlapping patent/publication key-word searches.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 53, 55, 57, 59, and 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

3. As a clarification, it is noted that the claims under examination are 1-5, 7, 8, 10-19, 21-49, 51, 52, and 56. Claims 6, 9, 20, 50, 54, 58, and 61-63 were previously cancelled.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 8, 49, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims encompass methods of detecting the broad genus of any possible mutation in the bone morphogenetic protein receptor-II (BMPR2) nucleic acid or protein, and correlating such a mutation with a pulmonary disease, giving birth to twins or triplets, or having a miscarriage. However, the specification only provides a written description of the specific mutations as set forth in Figure 4, and claimed in claims 10-19, 21-48, and 56. The two relevant inquiries regarding this issue are: have a representative number of species been described by complete structure; and if not, have a representative number of species been described by sufficient relevant identifying characteristics. It is submitted that the answer is in the negative for both of these questions, and as such the genus claims cannot be justified. While the specification discloses 19 gene-level mutations and their corresponding amino acid-level mutations, there is no description of any and every mutation which occurs in the BMPR2 gene/protein, not to mention which ones correlate with a specific disease/condition and which are neutral polymorphisms. In summary, at the time of the

invention the inventors were clearly not in possession of the subject matter embodied in the generic method claims.

5. Claim 56 is allowable. Claims 10-19 and 21-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art has been found teaching or suggesting detection of the specified mutations in the BMPR2 gene/protein and correlating them with predisposition to/affliction of a pulmonary disease, having twins or triplets, or having a miscarriage.

6. Loyd et al. (US 2002/0102576 A1 and WO 02/06534 A2), which are not prior art, are made of record as references of interest. These references disclose several BMPR2 mutations which are correlated with pulmonary hypertension, some of which are disclosed in the instant application and some of which are not. Wozney et al. (US 6,291,206) and Rosenbaum et al. (US 6,306,622) are also made of record as references of interest.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4242  
for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703-308-  
0196.

*Kenneth R. Horlick, Ph.D.*  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

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April 23, 2003